

Field Safety Notice 2025-1 Tekno-Medical

Checking the stock levels regarding

STANDARD DRESSING FORCEPS, 11,0CM

Dear Madam or Sir,

We, Tekno-Medical Optik-Chirurgie GmbH, hereby inform you of a field safety corrective action affecting the products listed below.

Sender (published by):

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstrasse 11, 78532 Tuttlingen, Germany
PRRC: Heike Karin Halm (safety@tekno-medical.com)
phone.: +49 (0) 7461 1701-23

Addressee:

This safety information concerns all distributors, users and relevant staff at healthcare facilities who use or distribute the product listed below.

Identification of the affected medical devices:

Commercial name	Part number	LOT number
STANDARD DRESSING FORCEPS 11,0CM	BA 000-11	00801387-T454424

Description of the problem

During an inspection of our stock, it was discovered that items may have been delivered which could potentially experience material problems under unfavourable circumstances.

It cannot be ruled out that the materials used do not meet the requirements specified by us as the manufacturer and may not be suitable or only partially suitable for the area of application.

Under unfavourable circumstances, it cannot be ruled out that the delivered instruments may not be suitable for reprocessing, or only to a limited extent.

What actions must the addressee take?

Please check your stock levels and the inventory of instruments currently in use immediately.

If you still have these items in stock or in use, please either return them to us for inspection or scrap them

Sharing the information described here:

Please ensure that all users of the above-mentioned products and other persons who need to be informed within your organisation are made aware of this **safety information**.
If you have supplied the products to third parties, please forward a copy of this information to them.

Please retain this information at least until the action has been completed.

The “Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)” has received a copy of this Field Safety Notice.

We apologise for any inconvenience this may cause. Please do not hesitate to contact us if you have any further questions.

Contact person:

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DE-MF-000005822

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Tuttlingen, 2025-09-29

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Tekno-Medical Optik-Chirurgie GmbH